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I also certify that the application is now proceeding in the name as identified herein.

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Signed

Dated 4 November 2004

GB 0325714.4

By virtue of a direction given under Section 30 of the Patents Act 1977, the application is proceeding in the name of:

CRANE PROCESS FLOW TECHNOLOGIES LTD,
Grange Road,
CWMBRAN,
Gwent,
NP44 3XX,
United Kingdom

Incorporated in the United Kingdom,

[ADP No. 08592149001]

and

ALFA LAVAL BIOKINETICS INC.,
1635 Market Street,
Suite 1500,
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PA 19103,
United States of America

Incorporated in USA - Delaware,

[ADP No. 08864332001]

Patents Form 1/77

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

1. Your reference — NG/22016

05NOV03 E849397-14 000190
P01/7700 0.00-0325714.4

2. Patent application number *(The Patent Office will fill in this part)* — 04 NOV 2003 — 0325714.4

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

CRANE PROCESS FLOW TECHNOLOGIES LTD

Grange Road
Cwmbran
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GB

28/4/04

SECTION 30(1) (1977 ACT) APPLICATION FILED

Patents ADP number *(if you know it)* 8592149001

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention — SINGLE USE DIAPHRAGM VALVE BODY

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

A A THORNTON & CO

235 HIGH HOLBORN
LONDON WC1V 7LE

75001

Patents ADP number *(if you know it)*

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
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YES

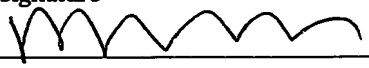
9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	8
Claim(s)	- DL
Abstract	-
Drawing(s)	8 + 8

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	-
Request for preliminary examination and search *(Patents Form 9/77)*	-
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature  Date 03/11/03

12. Name and daytime telephone number of person to contact in the United Kingdom: NIGEL GOODENOUGH - 01604 638242

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SINGLE USE DIAPHRAGM VALVE BODY

This invention relates to a diaphragm valve, and more particularly to a diaphragm valve having a body which is disposable.

A diaphragm valve comprises a valve body having a diaphragm opening to which a diaphragm is sealed. The valve body and diaphragm together define a flow passage which extends between an inlet port and an outlet port, both defined by the valve body. An operating mechanism is secured to the valve body for moving the diaphragm into sealing engagement with a seat provided on the valve body in order to close the flow passage to fluid flow.

Diaphragm valves have gained wide acceptance in many industries. One reason for the success of diaphragm valves in many industries is the fact that the line content is totally contained within the flow passage defined by the valve body and the diaphragm, and accordingly does not come into contact with any components of the valve other than the diaphragm and this body. This renders diaphragm valves particularly suitable for handling hazardous materials, or for use in applications where high levels of purity are required. For this reason, diaphragm valves have wide acceptance in the biotechnology industry.

It is of critical importance in the biotechnology industry in particular that process equipment can be thoroughly cleaned. Although existing diaphragm valves do admit to thorough cleaning by use of cleaning chemicals and/or steam, ensuring absolute cleanliness with existing diaphragm valves is difficult. It may, for example, be necessary, after initial cleaning, to dis-assemble a diaphragm valves in order to carry out a validity check on the sterility of the system. Such cleaning processes are both time consuming and subject to operator error. Even if, in a particular application, dis-assembly of the valve after initial cleaning is not considered to be necessary, the initial cleaning phase using cleaning chemicals and/or steam cleaning must be carried out thoroughly to achieve a high level of cleanliness. Accordingly, even if valve dis-

assembly is not necessary high quality cleaning procedures associated with process plant incorporating diaphragm valves are time consuming (and thus costly) and subject to operator error.

Accordingly, the present invention proposes a diaphragm valve in which the body and the diaphragm are "disposable". With such a valve, the valve in its entirety may be removed from a process line and the valve body and diaphragm replaced with a new valve body and diaphragms. Alternatively, only the valve body and diaphragm need be removed and replaced, whilst the remaining components of the valve are left in situ. Such replacement may take place instead of thorough cleaning of the valve or at specified intervals in order to prevent the build-up of contaminants within the valve.

Because it is a characteristic of diaphragm valves that the operating mechanism (compressor and actuator) does not come into contact with the line fluid it should not be necessary to dispose of these components when the body itself is disposed of.

Accordingly, it is the primary object of the present invention to provide a diaphragm valve in which the diaphragm and valve body may be disposed of and in which other components of the valve may be re-used in combination with a replacement valve body and diaphragm.

At first sight, the object of the present invention can be achieved simply by replacing a conventional valve body (which is typically of polished forged or cast stainless steel) with a moulded plastics valve body of the same profile. However, this is not possible because the mechanical characteristics of conventional metal valve bodies cannot be reproduced using plastics materials. In particular, the conventional arrangement whereby the closure diaphragm is sealed to the body by clamping the periphery of the diaphragm between respective flanges provided on the body and on the actuating mechanism is not possible if the body is formed of plastics material, in particular flexible plastics material.

In accordance with a first aspect of the present invention a diaphragm valve comprising: a valve body; a diaphragm which is sealed to the valve bodyto define a flow passage which extends between an inlet port and an outlet port, both defined

by the valve body; and operating mechanism secured to the valve body for moving the diaphragm into sealing engagement with a seat provided on the valve body in order to close the flow passage to fluid flow, is characterised in that the valve body and diaphragm are formed as a disposable assembly having a relatively less flexible region which forms a valve seat and a relatively more flexible region which forms a diaphragm which may be forced into engagement with the valve seat to close the flow passage to fluid flow, and a housing is provided for mechanically supporting the region of the valve body in which the seat area is defined.

The diaphragm valve of the present invention replaces the three main components of the conventional diaphragm valve, namely the body, the diaphragm and the operating mechanism, with three other fundamental components, namely a combined body/diaphragm component, the operating mechanism and a support for the combined body/diaphragm. This fundamental revision of the nature of the components enables the design of a disposable body/diaphragm component to be optimised for production and fluid flow characteristics even if this optimisation results in a body the mechanical strength of which would not be sufficient to withstand the forces conventionally applied to diaphragm valve bodies.

The invention will be better understood from the following description of preferred embodiments thereof, given by way of example only, reference being had to the accompanying drawings wherein:

Figure 1 illustrates a diaphragm body/diaphragm component and support of a first embodiment of the invention;

Figures 2, 3 and 4 show respectively an isometric view, a transverse cross-section, and a longitudinal cross-section of the valve body/diaphragm component of Figure 1;

Figure 5 illustrates an alternative valve body/diaphragm component;

Figure 6 illustrates an alternative valve body/diaphragm profiled to provide self-draining characteristics;

Figure 7 illustrates the components of Figure 1 secured to an operating mechanism; and

Figure 8 illustrates a modified embodiment of the invention in which means are provided for forming a mechanical connection between a flexible portion of the body/diaphragm component and a compressor.

Referring firstly to Figure 1 there is illustrated a diaphragm valve 1 from which the operating mechanism has been removed in the interests of clarity. The remaining components of the valve comprise a combined body and diaphragm member 2 and a support 3 formed by an upper support member 4 and a lower support member 5. The upper support member 4 defines an aperture 6 in which, in use, a diaphragm compressor is located. Means (not shown) are in practice provided for securing the operating mechanism to the support 3.

The body and diaphragm member 2 is illustrated in greater detail in Figures 2-4. The member 2 is moulded from a synthetic material, for example a synthetic thermo-plastic material. The material may be un-reinforced or reinforced by fibre or other reinforcing materials depending on the circumstances and design in question. It will be seen that the member 2 defines inlet and outlet ports 7, 8 respectively, and a flow passage 9 which connects the inlet and outlet ports. As illustrated, the member 2 is symmetrical about a transverse plane of symmetry and accordingly either of the ports 7, 8 may function as an inlet port whilst the other port functions as an outlet port.

A transverse cross-section in the central region of the member 2 is illustrated in Figure 3. In this transverse region the body includes a relatively thick lower portion 10 which defines, on the upper surface thereof, a valve seat 11. The valve seat 11 may be constituted by a portion of a generally smooth flow passage, or may be formed by the upper surface of a weir moulded into the flow passage. Opposite the seat 11 is a relatively flexible portion 12 of the body which can be moved, by a suitable operating mechanism into sealing engagement with the seat 11 to close the flow passage 9 to fluid flow. The relatively flexible nature of the region 12 is achieved by a combination of the profile of the member 2 at this region and by a relatively thin section of material

at this region. Similarly, the relatively rigid region 10 is formed by a relatively thick section of material and/or reinforcement provided in this region.

It will be noted that wings 13, 14 extend laterally outwardly from the remaining portions of the member 2. The wings at their widest at the central portion at which the cross-section of Figure 3 is taken and reduced in lateral extent towards the opposite ends of the member 2, eventually blending into the profile of the member 2 adjacent the end regions 15, 16 of the body. The purpose of the wings 13, 14 is to provide additional strengthening of the valve body, particularly in the region of the cross-section illustrated in Figure 3.

The thin cross-section of the region 12 blends, in the longitudinal direction, into the full cross-section of the wall of the body, reaching the full cross-section by the end regions 15 and 16, as illustrated in the longitudinal cross-section of Figure 4.

The required contrast between the relatively rigid region 10 and the relatively flexible region 12 may be achieved by use only of the shaping of these regions, and in particular the thickness of material in these regions, or may be achieved by other means, for example the inclusion of reinforcing material within the relatively rigid regions and/or by differences in the plastics material utilised in the respective regions. It may, for example, be possible to mould a unitary body in which the relatively flexible region 12 is formed from a different polymer or different grade of the same polymer as that used for the relatively rigid regions. This technique may be used in association with the variable wall thick technique referred to above. The important characteristic is that the member 2 defines a relatively rigid region and a relatively flexible region which can be brought into engagement with the rigid region to interrupt fluid flow through the flow passage 9.

The member 2 illustrated in Figures 2-4 may be moulded as a single unitary moulding by use of suitable mould and core tools. In the alternative, the member may be formed by two components, one of which has the form illustrated in Figure 4 and the other of which is a mirror image of that component about the longitudinal plane of the section of Figure 4. Two such components can be moulded separately and joined

together after moulding by a welding process.

Turning now to Figure 5 an alternative approach to the design and construction of a combined body and diaphragm member is illustrated. In this case, the body 20 is moulded from one synthetic material and the diaphragm 21 is moulded from a different material which is, nonetheless, compatible with the material of the body 20 so that the two components may be welded together to form a unitary body and diaphragm member. The advantage of the Figure 5 arrangement is that the materials from which the body 20 and diaphragm 21 are made may, to an extent, be optimised in light of the respective function these components are to perform, thereby providing a relatively rigid seat area and a relatively flexible diaphragm area. In practice, after the body 20 and diaphragm 21 have been formed and united by an appropriate process the resultant combined member will be used in association with a support appropriately shaped to the profile of the combined member in order to provide the necessary mechanical support in the region of the valve seat 22.

Referring now to Figure 6, an alternative form of combined body and diaphragm member 23 is illustrated. This design generally corresponds to that of the previous embodiments in that it may be a unitary moulding, an assembly of two substantially symmetrical moulded parts, or an assembly of two separate mouldings (body and diaphragm). In this case, however, the body is profiled to provide a substantially flat invert surface 24 so that the valve will have "self-draining" characteristics.

Figure 7 illustrates a complete valve comprising a combined body and diaphragm member 30, a support 31, and an operating mechanism 32. The support 31 comprises a lower support member 33 which offers mechanical support for the relatively rigid portions 34 of the valve body and the wings 35 (only one of which is visible in Figure 7) and an upper portion 36 which serves to locate the component relative to the support 31 and defines a cavity 37 in which the compressor 38 of the operating mechanism 32 is located. Suitable means (for example screws) are provided for attaching the upper part 36 of the support 31 to a flange 39 provided on the

operating mechanism 32. The lower portion 33 of the support 31 is secured to the upper portion 36 of the support 31 by one or more releasable clamps. For example, the lower portion 33 may be secured to the upper portion 36 by means of a hinge along one edge and by means of a releasable over-centred toggle clamp along the opposite edge. With such an arrangement, the lower portion 33 can be readily separated from the upper portion 36 to permit removal of the body and diaphragm component 30 for appropriate disposal and replacement.

In the arrangement illustrated in Figure 7 the compressor 38 abuts the flexible region of the body and diaphragm member 30, but no mechanical coupling is provided between these respective components. Accordingly, the valve of Figure 7 would be incapable of opening against a sub-ambient pressure within the valve body. To avoid this problem an arrangement for mechanically coupling the flexible portion of the body and diaphragm member to the compressor may be provided. Such an arrangement is illustrated in Figure 8. In this case, a cup 40 is moulded integrally with the body and diaphragm member 41 in the flexible region thereof and is, in use, secured by a snap-fit connection to a button 42 provided on the compressor. With such an arrangement the compressor can readily be coupled to and released from the diaphragm and body member 30.

In the above illustrated embodiments of the invention the body and diaphragm component is illustrated as having plain cylindrical ends. Such ends would, of course, require appropriate coupling to secure them into a pipework system. The exact form of the couplings will depend on the application and many such forms of couplings will be apparent to those skilled in the art.

In a particularly preferred embodiment of the invention arrangements are put in place to permanently mark each body and diaphragm assembly as it is placed within the support. Such means may, for example, comprise a knife blade provided on the support which cuts a notch or makes an incision in one of the wings of the body and diaphragm member. The object of this arrangement is to ensure that a previously used component will not accidentally be re-used.

Whilst the invention has been described in the context of a 2-port valve it is to be understood that the present invention is applicable to other forms of valve, for example valves with three or more ports controlled by one or more diaphragms. The exact arrangements of the valve body, diaphragm and operating mechanism will, of course, be determined by the number of ports present in the valve, but the general concepts of the present invention may be applied to such multi-port valves and the present application is to be construed as encompassing such multi-port valves.

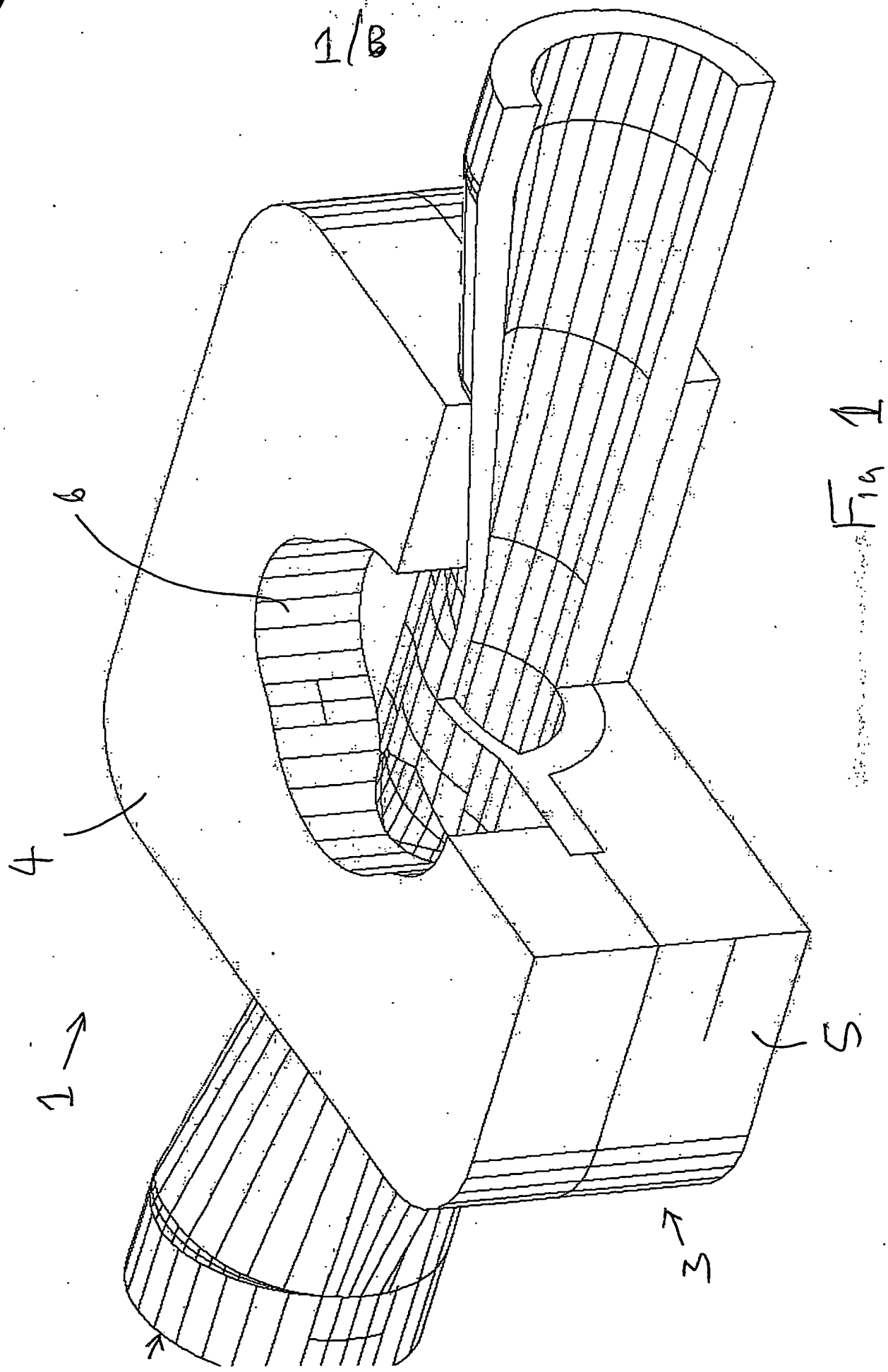

Fig 1

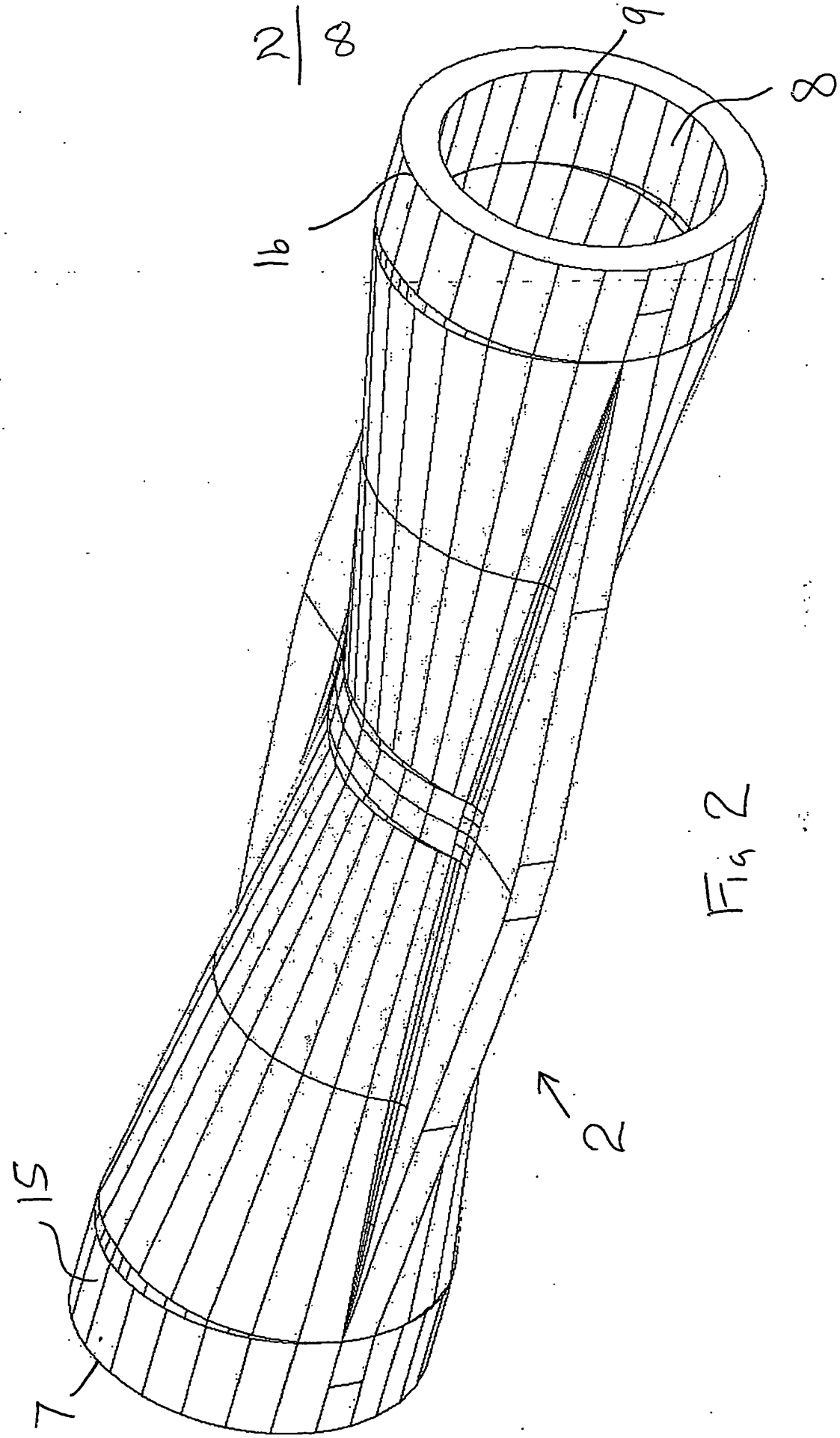

Fig 2

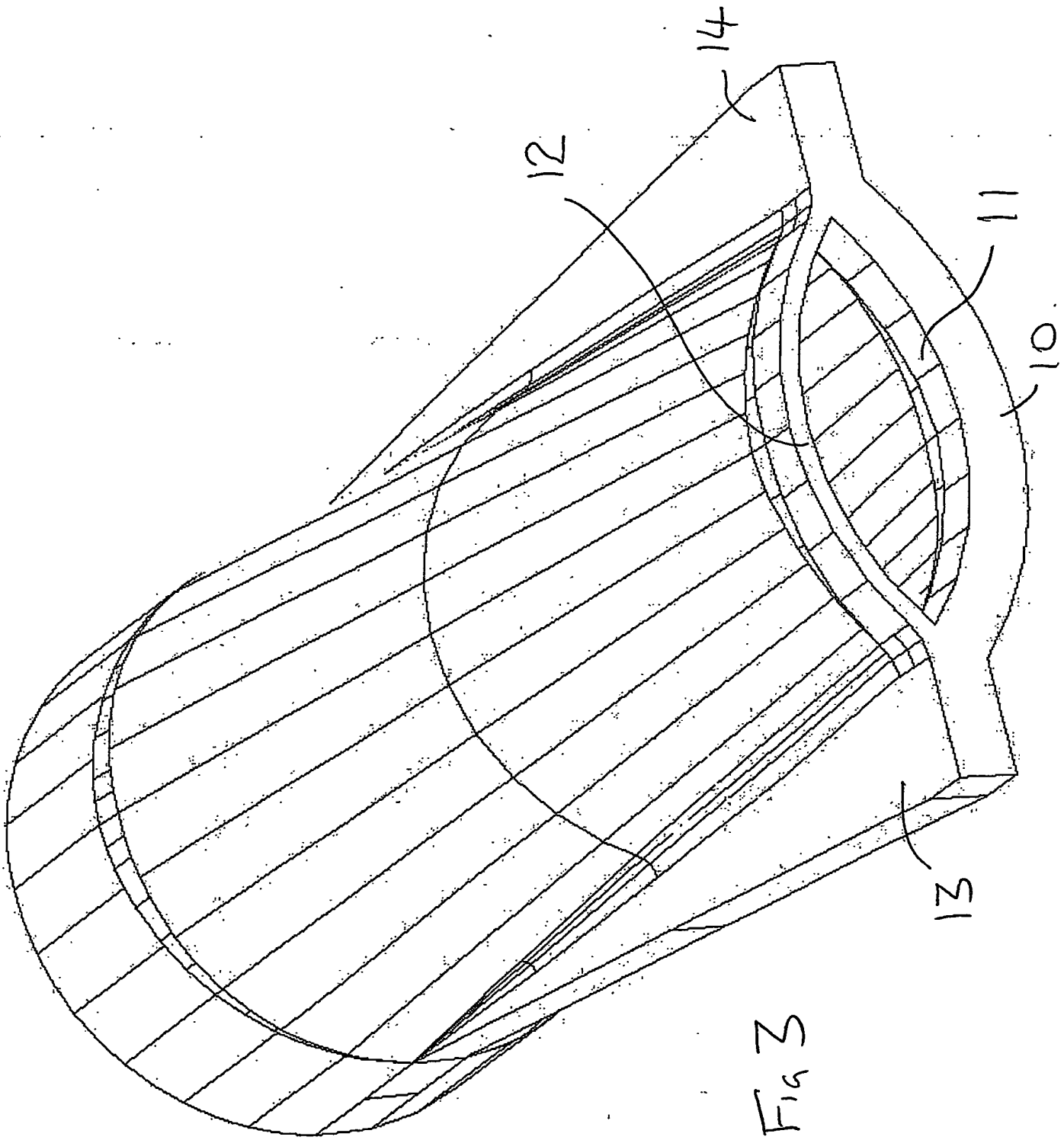

Fig 3

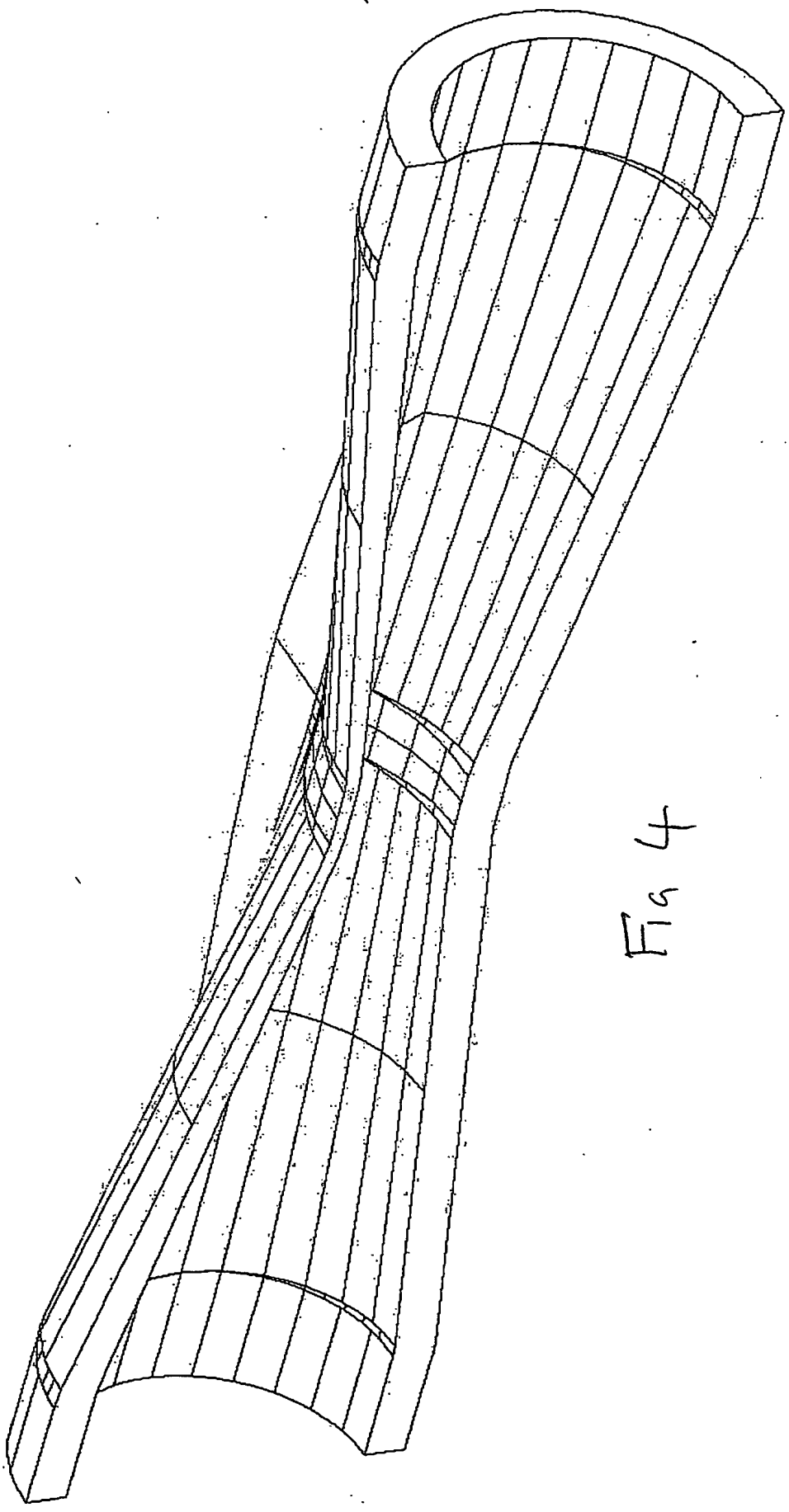

Fig 4

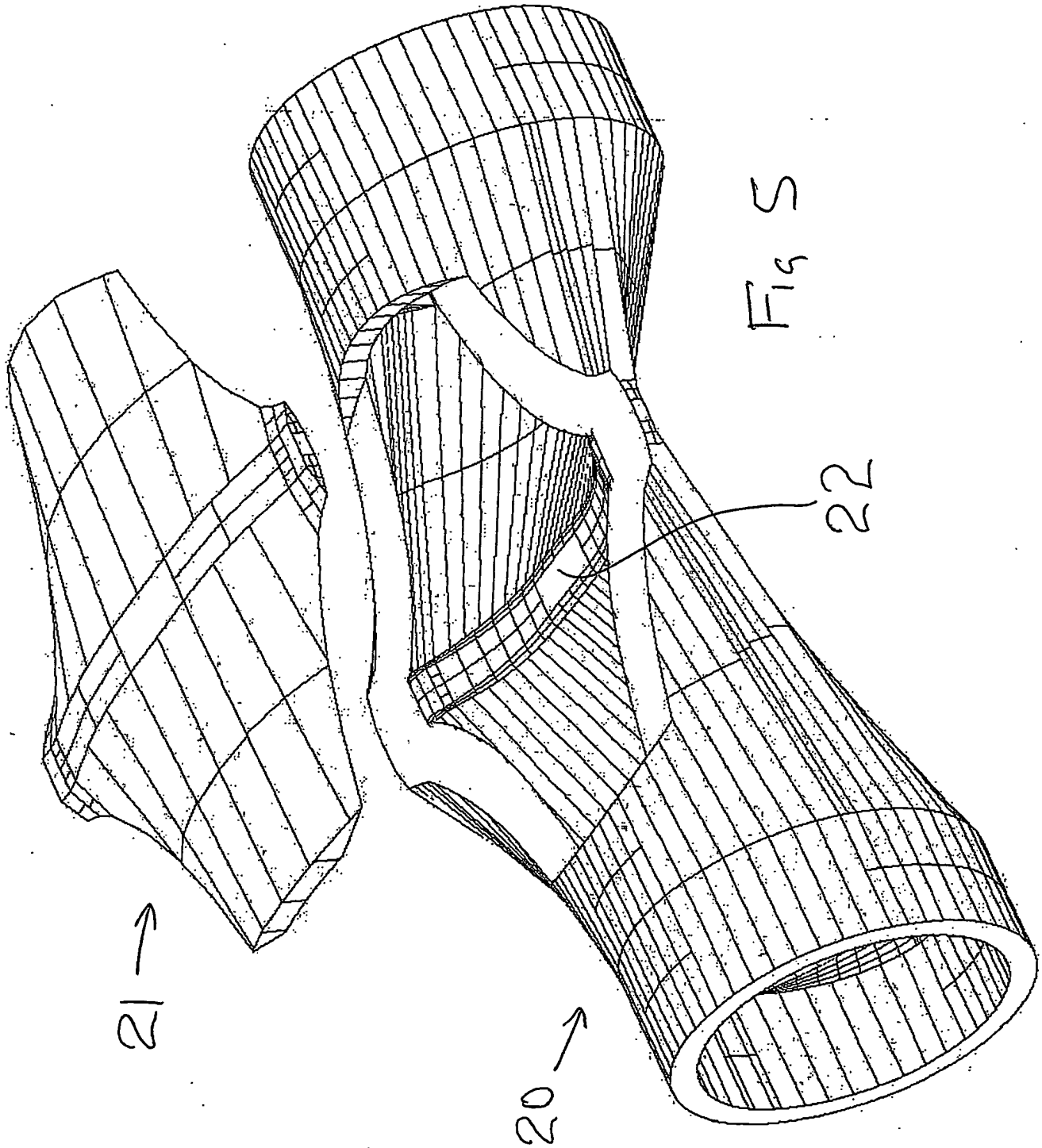

Fig 5

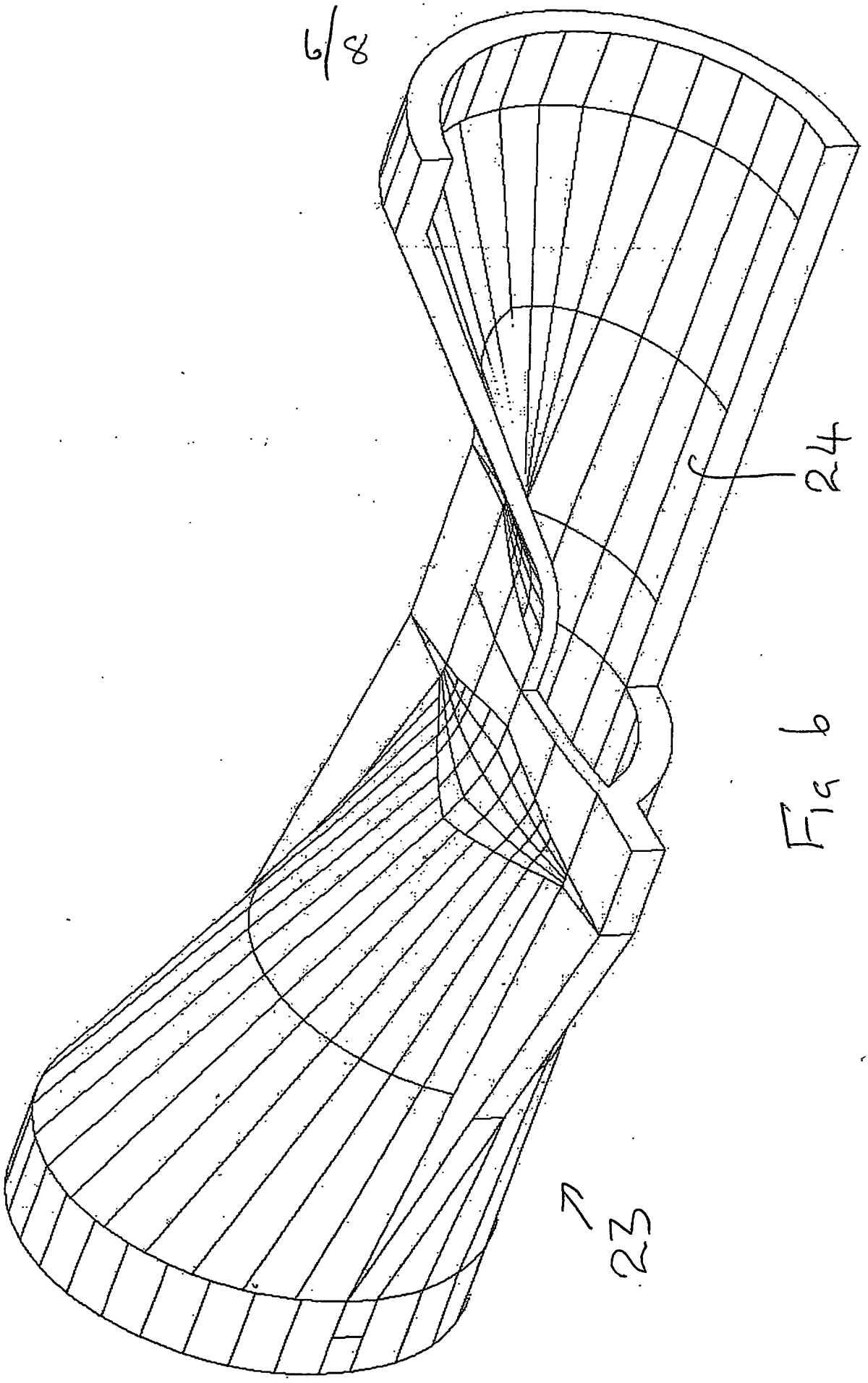

Fig 6

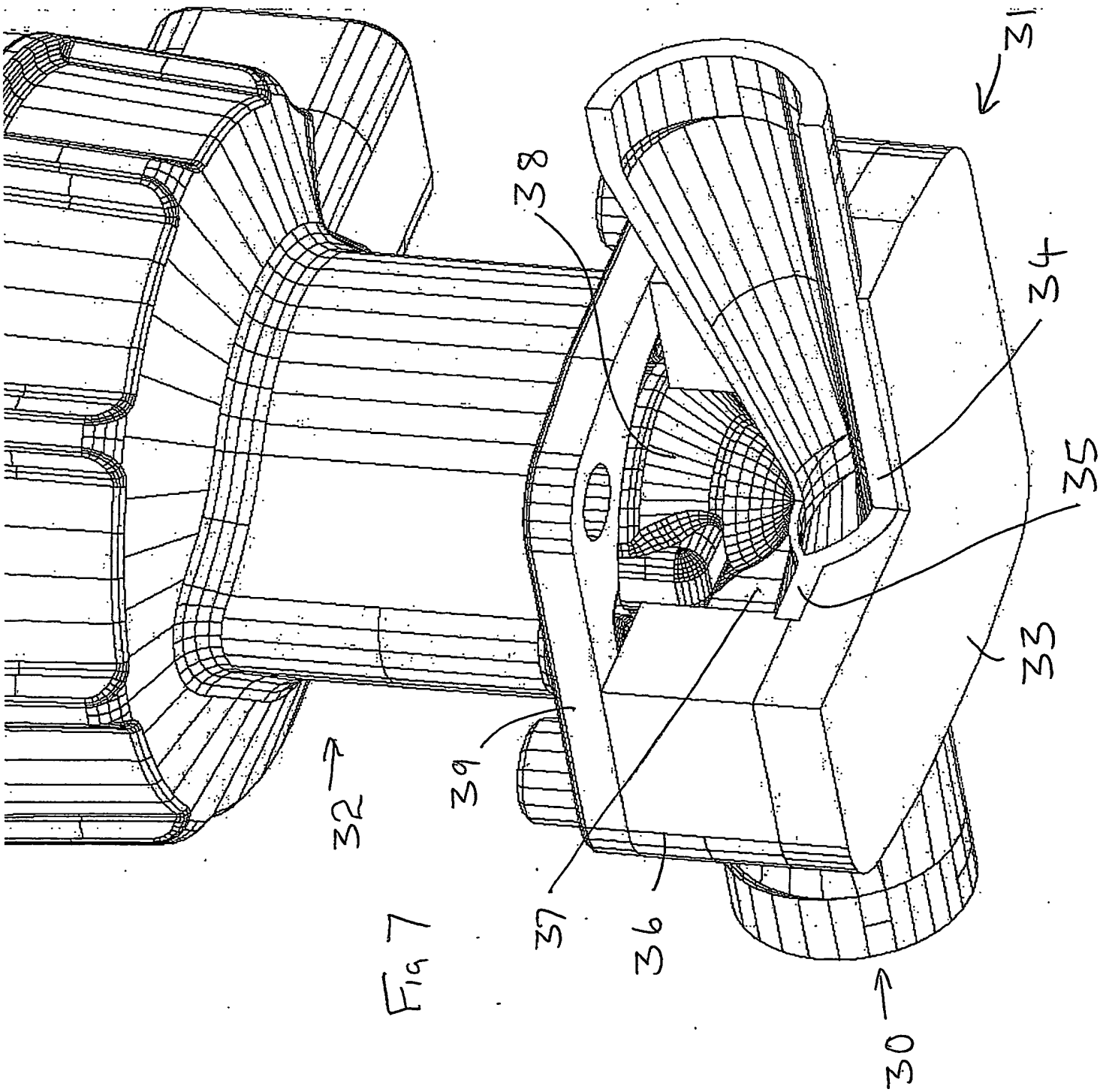

Fig 7

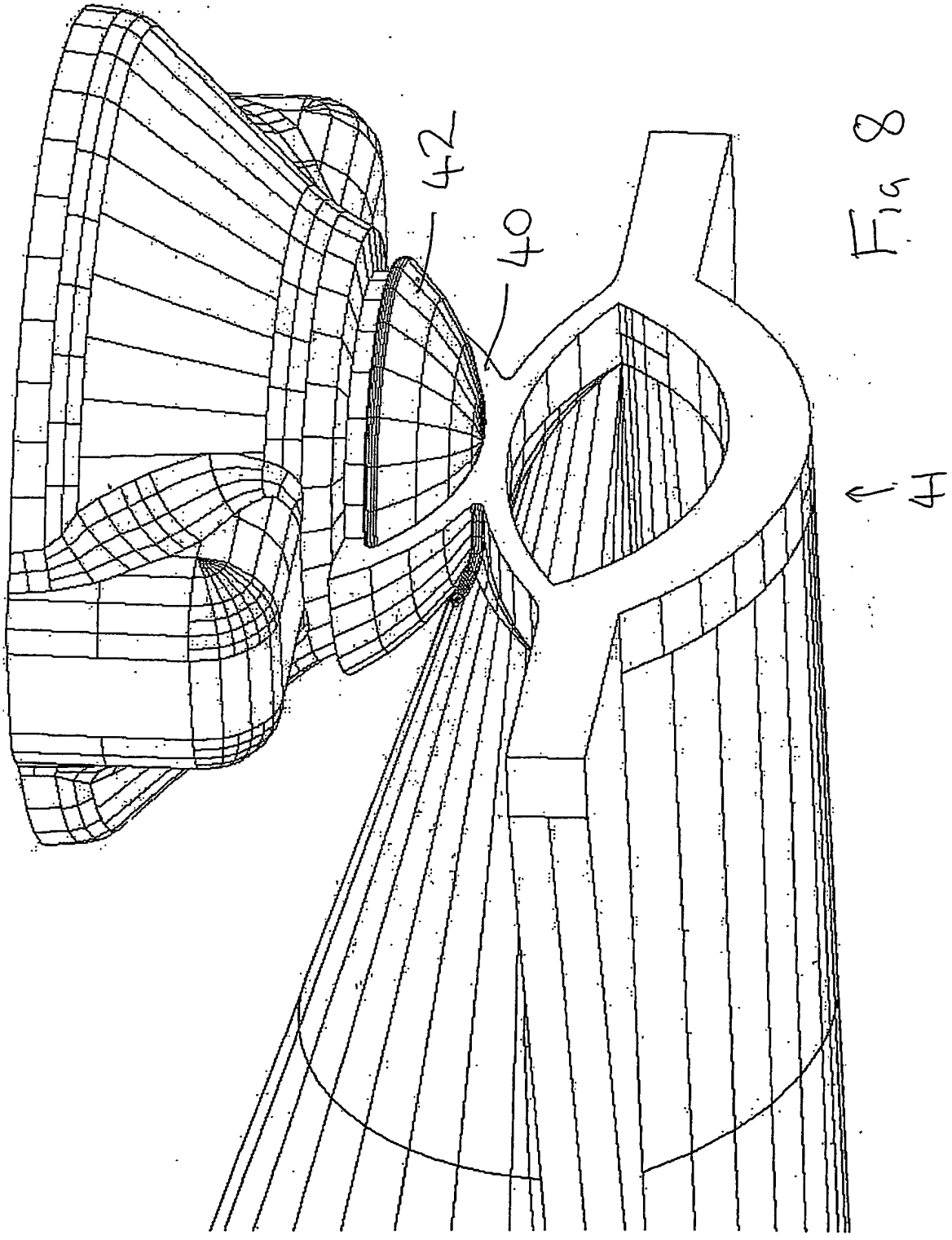

Fig 8